

REMARKS

Claims 1-4 are pending in the application. Claims 1-4 are rejected. Claims 1-4 are canceled herein without prejudice and new claims 5-42 are added. No new material is added by the amendments herein. Applicants respectfully submit that claims 5-42, as added herein, are patentably distinct from the cited prior art and the prior art made of record.

Claim Rejections under 35 USC §102 as being anticipated by Winston

Claims 1-4 are rejected under 35 USC §102(b) as being anticipated by Winston et al., U.S. Patent number 5,951,482 ("Winston"). Applicants submit that Winston discloses systems and methods for advancing a guide wire through body tissue (Abstract). The systems use a guide wire that includes an interferometric guidance system and a tissue removal member. The interferometric guidance system includes first and second optic fibers, with the first optic fiber positioned within a blood vessel to be treated and the second optic fiber positioned outside the blood vessel (column 5, lines 35-42). The tissue removal member is a treatment laser like an excimer laser that ablates tissue to open a channel through the plaque of an occlusion. The tissue removal member can also be a metal wire for use in picking its way through the plaque (column 1, line 66 to column 2, line 35).

Applicants respectfully submit that as Winston describes a system for ablating plaque of an occlusion or picking its way through plaque from a position in the true lumen of a vessel proximal to an occlusion Winston fails to disclose a catheter system for use in forming a pathway between a sub-intimal space of a blood vessel and a true lumen of the blood vessel as described in new claims 24, 36, 37, and 38 (emphasis added). Therefore, Winston fails to disclose a catheter system comprising an incising element translatable across a portion of a port of a distal endpiece, the incising element configured to form an incision in tissue separating the sub-intimal space from the true lumen, the incision having separate and distinct end points and forming a pathway between the sub-intimal space and the true lumen, wherein the tissue remains external to the port subsequent to forming the incision. Further with regard to claims 37 and 38, Winston

fails to disclose a catheter system in which the catheter lumen is configured to translate vacuum from a proximal end to a distal end of the catheter body. Thus, applicants respectfully submit that new claims 24, 36, 37, and 38 are patentable over Winston. (Emphasis added). Additionally, as new claims 25-35 depend from new claim 24, claims
5 25-35 are patentable over Winston.

Applicants also respectfully submit that as Winston describes a system for ablating plaque of an occlusion or picking its way through plaque Winston fails to disclose a catheter system for use in forming a pathway between a sub-intimal space of a blood vessel and a true lumen of the blood vessel as described in new claim 39 (emphasis
10 added). Therefore, Winston fails to disclose a catheter system comprising an excising element translatable across a portion of a port of a distal endpiece, the excising element configured to excise tissue separating the sub-intimal space from the true lumen to form a pathway between the sub-intimal space and the true lumen. Thus, applicants respectfully submit that new claim 39 is patentable over Winston. (Emphasis added). Additionally,
15 as claims 40 and 41 depend from claim 39, claims 40 and 41 are patentable over Winston.

Applicants respectfully submit that as Winston describes a method for ablating plaque of an occlusion or picking its way through plaque Winston fails to disclose a method for forming a pathway from a sub-intimal space of a blood vessel into a true lumen of the blood vessel as described in claims 5, 19, 22, and 42. Therefore, Winston
20 fails to disclose a method comprising positioning a catheter system within the sub-intimal space, the catheter system including an internal incising element that is translatable across a portion of a port in a distal region of the catheter system, and forming an incision in tissue separating the sub-intimal space from the true lumen using the incising element, the incision having separate and distinct end points and forming a pathway between the
25 sub-intimal space and the true lumen, wherein the tissue remains external to the port subsequent to forming the incision. Thus, applicants respectfully submit that claims 5, 19, 22, and 42 are patentable over Winston. (Emphasis added). Additionally, as claims 6-18 depend from new claim 5, claims 6-18 are patentable over Winston.

Applicants respectfully submit that as Winston describes a method for ablating
30 plaque of an occlusion or picking its way through plaque Winston fails to disclose a method for forming a pathway from a sub-intimal space of a blood vessel into a true

lumen of the blood vessel as described in new claims 20 and 21. Therefore, Winston fails to disclose a method comprising positioning a catheter system within the sub-intimal space, the catheter system including an internal excising element that is translatable across a portion of a port in a distal region of the catheter system, and excising an area of
5 tissue separating the sub-intimal space from the true lumen using the excising element, the excised area of tissue generating a pathway between the sub-intimal space to the true lumen. Thus, applicants respectfully submit that new claims 20 and 21 are patentable over Winston. (Emphasis added).

Applicants respectfully submit that as Winston describes a method for ablating
10 plaque of an occlusion or picking its way through plaque Winston fails to disclose a method for establishing a pathway through a chronic total occlusion of a blood vessel, the pathway connecting a first region of a true lumen of the blood vessel which is proximal to the occlusion to a second region of the true lumen distal to the occlusion via an extra-
15 luminal pathway within the vessel as described in new claim 23. Therefore, Winston fails to disclose a method comprising forming a track longitudinally from the first region of the true lumen through the occlusion and into a sub-intimal space distal to the occlusion, positioning a catheter system within the sub-intimal space using the track, and
20 applying a vacuum through a lumen and a port of the catheter system, evacuating fluid from the sub-intimal space and bringing the sub-intimal tissue into intimate contact with the port. Thus, applicants respectfully submit that new claim 23 is patentable over Winston. (Emphasis added).

Claim Rejections under 35 USC §102 as being anticipated by Yock

Claims 1-4 are rejected under 35 USC §102(b) as being anticipated by Yock et al.,
25 U.S. Patent number 5,029,588 ("Yock"). Applicants submit that Yock discloses vascular catheters for use in laser ablation angioplasty (column 4, lines 55-62). The Yock catheters include ultrasonic imaging capabilities and optical waveguides for delivering laser energy for ablating vascular obstructions (Abstract). The catheters of Yock use ultrasonic imaging to specifically direct laser energy to vascular obstructions in order to
30 remove or lessen such obstructions without damage to the surrounding blood vessel wall (column 4, lines 55-62).

Applicants respectfully submit that as Yock describes laser ablation angioplasty catheters for ablating plaque of an occlusion with laser energy from a position in the true lumen of a vessel proximal to an occlusion Yock fails to disclose a catheter system for use in forming a pathway between a sub-intimal space of a blood vessel and a true lumen
5 of the blood vessel as described in new claims 24, 36, 37, and 38 (emphasis added). Therefore, Yock fails to disclose a catheter system comprising an incising element translatable across a portion of a port of a distal endpiece, the incising element configured to form an incision in tissue separating the sub-intimal space from the true lumen, the incision having separate and distinct end points and forming a pathway between the sub-
10 intimal space and the true lumen, wherein the tissue remains external to the port subsequent to forming the incision. Further with regard to claims 37 and 38, Yock fails to disclose a catheter system in which the catheter lumen is configured to translate vacuum from a proximal end to a distal end of the catheter body. Thus, applicants respectfully submit that new claims 24, 36, 37, and 38 are patentable over Yock.
15 (Emphasis added). Additionally, as new claims 25-35 depend from new claim 24, claims 25-35 are patentable over Yock.

Applicants also respectfully submit that as Yock describes a system for performing laser ablation angioplasty Yock fails to disclose a catheter system for use in forming a pathway between a sub-intimal space of a blood vessel and a true lumen of the
20 blood vessel as described in new claim 39 (emphasis added). Therefore, Yock fails to disclose a catheter system comprising an excising element translatable across a portion of a port of a distal endpiece, the excising element configured to excise tissue separating the sub-intimal space from the true lumen to form a pathway between the sub-intimal space and the true lumen. Thus, applicants respectfully submit that new claim 39 is patentable
25 over Yock. (Emphasis added). Additionally, as claims 40 and 41 depend from claim 39, claims 40 and 41 are patentable over Yock.

Applicants respectfully submit that as Yock describes a method for laser ablation angioplasty Yock fails to disclose a method for forming a pathway from a sub-intimal space of a blood vessel into a true lumen of the blood vessel as described in claims 5, 19,
30 22, and 42. Therefore, Yock fails to disclose a method comprising positioning a catheter system within the sub-intimal space, the catheter system including an internal incising

element that is translatable across a portion of a port in a distal region of the catheter system, and forming an incision in tissue separating the sub-intimal space from the true lumen using the incising element, the incision having separate and distinct end points and forming a pathway between the sub-intimal space and the true lumen, wherein the tissue remains external to the port subsequent to forming the incision. Thus, applicants respectfully submit that claims 5, 19, 22, and 42 are patentable over Yock. (Emphasis added). Additionally, as claims 6-18 depend from new claim 5, claims 6-18 are patentable over Yock.

Applicants respectfully submit that as Yock describes a method for ablating vascular obstructions Yock fails to disclose a method for forming a pathway from a sub-intimal space of a blood vessel into a true lumen of the blood vessel as described in new claims 20 and 21. Therefore, Yock fails to disclose a method comprising positioning a catheter system within the sub-intimal space, the catheter system including an internal excising element that is translatable across a portion of a port in a distal region of the catheter system, and excising an area of tissue separating the sub-intimal space from the true lumen using the excising element, the excised area of tissue generating a pathway between the sub-intimal space to the true lumen. Thus, applicants respectfully submit that new claims 20 and 21 are patentable over Yock. (Emphasis added).

Applicants respectfully submit that as Yock describes a method for ablating vascular obstructions Yock fails to disclose a method for establishing a pathway through a chronic total occlusion of a blood vessel, the pathway connecting a first region of a true lumen of the blood vessel which is proximal to the occlusion to a second region of the true lumen distal to the occlusion via an extra-luminal pathway within the vessel as described in new claim 23. Therefore, Yock fails to disclose a method comprising forming a track longitudinally from the first region of the true lumen through the occlusion and into a sub-intimal space distal to the occlusion, positioning a catheter system within the sub-intimal space using the track, and applying a vacuum through a lumen and a port of the catheter system, evacuating fluid from the sub-intimal space and bringing the sub-intimal tissue into intimate contact with the port. Thus, applicants respectfully submit that new claim 23 is patentable over Yock. (Emphasis added).

Claim Rejections under 35 USC §102 as being anticipated by Snow

Claims 1-4 are rejected under 35 USC §102(e) as being anticipated by Snow et al., U.S. Patent number 6,299,622 ("Snow"). Applicants submit that Snow discloses an atherectomy catheter for cutting and removing material from a body lumen. The
5 atherectomy catheter disclosed by Snow includes a catheter body, a cutting blade, and an imaging device. The cutting blade is mounted on the catheter body and configured to move between a material capture (open) position and a closed position in which the cutting blade severs the material. The severed material is removed from the body lumen in the atherectomy catheter. (Abstract; column 2, line 30 to column 3, line 12; column 5,
10 line 35 to column 6, line 30).

Applicants respectfully submit that as Snow describes atherectomy catheters for cutting and removing material from a body lumen Snow fails to disclose a catheter system for use in forming a pathway between a sub-intimal space of a blood vessel and a true lumen of the blood vessel as described in new claims 24, 36, 37, and 38 (emphasis
15 added). Therefore, Snow fails to disclose a catheter system comprising an incising element translatable across a portion of a port of a distal endpiece, the incising element configured to form an incision in tissue separating the sub-intimal space from the true lumen, the incision having separate and distinct end points and forming a pathway between the sub-intimal space and the true lumen. Also, as the catheters of Snow remove
20 severed material from the body lumen inside the catheter, Snow fails to disclose a catheter system wherein the incised tissue remains external to the port subsequent to formation of the incision. Further with regard to claims 37 and 38, Snow fails to disclose a catheter system in which the catheter lumen is configured to translate vacuum from a proximal end to a distal end of the catheter body. Thus, applicants respectfully submit
25 that new claims 24, 36, 37, and 38 are patentable over Snow. (Emphasis added). Additionally, as new claims 25-35 depend from new claim 24, claims 25-35 are patentable over Snow.

Applicants also respectfully submit that as Snow describes a system for cutting and removing material from a body lumen Snow fails to disclose a catheter system for
30 use in forming a pathway between a sub-intimal space of a blood vessel and a true lumen of the blood vessel as described in new claim 39 (emphasis added). Therefore, Snow

fails to disclose a catheter system comprising an excising element translatable across a portion of a port of a distal endpiece, the excising element configured to excise tissue separating the sub-intimal space from the true lumen to form a pathway between the sub-intimal space and the true lumen. Thus, applicants respectfully submit that new claim 39 is patentable over Snow. (Emphasis added). Additionally, as claims 40 and 41 depend from claim 39, claims 40 and 41 are patentable over Snow.

Applicants respectfully submit that as Snow describes a method for cutting and removing material from a body lumen Snow fails to disclose a method for forming a pathway from a sub-intimal space of a blood vessel into a true lumen of the blood vessel as described in claims 5, 19, 22, and 42. Therefore, Snow fails to disclose a method comprising positioning a catheter system within the sub-intimal space, the catheter system including an internal incising element that is translatable across a portion of a port in a distal region of the catheter system, and forming an incision in tissue separating the sub-intimal space from the true lumen using the incising element, the incision having separate and distinct end points and forming a pathway between the sub-intimal space and the true lumen, wherein the tissue remains external to the port subsequent to forming the incision. Thus, applicants respectfully submit that claims 5, 19, 22, and 42 are patentable over Snow. (Emphasis added). Additionally, as claims 6-18 depend from new claim 5, claims 6-18 are patentable over Snow.

Applicants respectfully submit that as Snow describes a method for cutting and removing material from a body lumen Snow fails to disclose a method for forming a pathway from a sub-intimal space of a blood vessel into a true lumen of the blood vessel as described in new claims 20 and 21. Therefore, Snow fails to disclose a method comprising positioning a catheter system within the sub-intimal space, the catheter system including an internal excising element that is translatable across a portion of a port in a distal region of the catheter system, and excising an area of tissue separating the sub-intimal space from the true lumen using the excising element, the excised area of tissue generating a pathway between the sub-intimal space to the true lumen. Thus, applicants respectfully submit that new claims 20 and 21 are patentable over Snow. (Emphasis added).

Applicants respectfully submit that as Snow describes a method for cutting and removing material from a body lumen Snow fails to disclose a method for establishing a pathway through a chronic total occlusion of a blood vessel, the pathway connecting a first region of a true lumen of the blood vessel which is proximal to the occlusion to a second region of the true lumen distal to the occlusion via an extra-luminal pathway within the vessel as described in new claim 23. Therefore, Snow fails to disclose a method comprising forming a track longitudinally from the first region of the true lumen through the occlusion and into a sub-intimal space distal to the occlusion, positioning a catheter system within the sub-intimal space using the track, and applying a vacuum through a lumen and a port of the catheter system, evacuating fluid from the sub-intimal space and bringing the sub-intimal tissue into intimate contact with the port. Thus, applicants respectfully submit that new claim 23 is patentable over Snow. (Emphasis added).

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully submit that new claims 5-42 are in condition for allowance. Thus, allowance of the claims is requested. If in the opinion of Examiner Ho a telephone conference would expedite the prosecution of the subject application, or if there are any issues that remain to be resolved prior to allowance of the claims, Examiner Ho is encouraged to call Rick Gregory at (408) 236-6646.

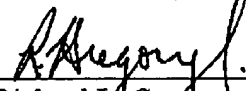
A Petition for Extension of Time Under 37 CFR 1.136(a) is enclosed herewith in duplicate for a one month extension of time.

AUTHORIZATION TO CHARGE DEPOSIT ACCOUNT

Please charge deposit account 501914 for any fees due in connection with this Office Action response.

Date: May 22, 2004

Respectfully submitted,
Shemwell Gregory & Courtney LLP


Richard L. Gregory, Jr.

Reg. No. 42,607
Tel. 408-236-6646